

Abbott – Recall of FreeStyle Libre® Readers

Summary

- On April 12, 2023, the FDA announced a recall of FreeStyle Libre, FreeStyle Libre 14 day Flash, and FreeStyle Libre 2 Flash Glucose Management Systems' **Reader devices**, which use rechargeable batteries.
- The batteries may get extremely hot, spark, or catch on fire if not properly stored, charged, or used with its Abbott provided USB cable and power adapter. The recall does not affect any of the FreeStyle Libre family of sensors.
- The FreeStyle Libre Glucose Monitoring Systems are used to provide continuous monitoring of glucose levels. These devices help people manage diabetes by detecting trends and tracking patterns in glucose levels so treatment can be adjusted as needed.
- The **Reader** is a handheld device that gets blood glucose readings from the sensor. The sensor is worn by the patient and the patient uses the Reader to scan the sensor for blood glucose readings.

Suggested talking points to members

1. **What are the FreeStyle Libre Glucose Management Systems used for?**

The FreeStyle Libre Glucose Management Systems are used to monitor blood glucose levels. These devices help people manage diabetes by detecting trends and tracking patterns in glucose levels so treatment can be adjusted as needed.

2. **What are the Readers used for?**

The Reader is a small handheld device that collects real-time glucose readings directly from a sensor worn on the back of a person's upper arm, allowing them to manage their diabetes by seeing their glucose readings on a screen.

3. **Why are the FreeStyle Libre Readers being recalled?**

Abbott is recalling the FreeStyle Libre reader devices, which use rechargeable batteries. The batteries may get extremely hot, spark, or catch on fire if not properly stored, charged, or used with its Abbott provided USB cable and power adapter.

If you are **not** experiencing problems with the Abbott provided Reader and you have the Abbott provided USB cable and power adapter, you can continue to use the Abbott provided Reader, USB cable, and power adapter .

4. Does this recall impact the FreeStyle Libre Sensors?

No. The recall does not affect any of the FreeStyle Libre sensors.

5. How can I tell if my Reader needs to be replaced?

Stop using the Reader and switch to a back-up method **ONLY** if you experience any of the following:

- The Reader appears damaged or cracked
- If there is visible swelling of the Reader
- If the Reader gets too hot to hold
- If the Reader is no longer able to hold a charge (for example, if it turns off unexpectedly or immediately after charging)
- You do not have the Abbott provided USB cable and power adapter

If the Reader is damaged or a replacement USB cable or power adapter are needed, call Abbott at **1-855-632-8658** (8:00 a.m. - 8:00 p.m. EST, 7 days a week) to request a replacement.

You can also visit www.freestylebattery.com to check if your Reader needs to be replaced.

6. What are the potential safety concerns with the Reader?

If the Reader is not properly stored, charged, or used with the Abbott-provided yellow USB cable and charger, a potential exists for battery swelling and, in rare cases, extreme overheating, which may pose a fire hazard.

See photo of the Abbott-provided USB cable and charger on the following pages.

7. Should I continue using my Reader?

If you are **not** experiencing problems with the Abbott provided Reader and you have the Abbott provided USB cable and power adapter, you can continue to use the Abbott provided Reader, USB cable, and power adapter.

The Readers are safe when properly stored, charged and used only with their accompanying USB cable and power adapter, as outlined at **www.FreeStyleBattery.com**.



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8. How do I avoid the potential for battery issues (i.e., swelling, leakage and extreme overheating and/or fire) with my Reader?

Abbott recommends the following:

- Charge the Reader battery by ONLY using the Abbott supplied USB cable and power adapter. *See photo of the Abbott-provided USB cable and charger on following pages.*
- DO NOT expose the Reader, power adapter or yellow USB cable to water or other liquids.
- Store the Reader between -4 °F and 140 °F.
- DO NOT place the Reader in water or other liquids.
- Avoid getting dust, dirt, blood, control solution, water, bleach, or any other substance in the test strip or USB port.
- Review the revised user guide and labeling here at www.freestyle.abbott/us-en/support.
- Visit www.FreeStyleBattery.com to follow steps to perform a Reader Test to determine if your current Reader needs to be replaced

9. Will the FreeStyle Libre Readers still be available?

Yes.

10. Will the FreeStyle Libre Glucose Monitoring Systems still be available?

Yes.

11. Who should I contact for medical questions?

If you have medical questions, please contact your doctor.

12. Where can I find more information about this recall?

For more information about this recall, please contact your pharmacy or Abbott:

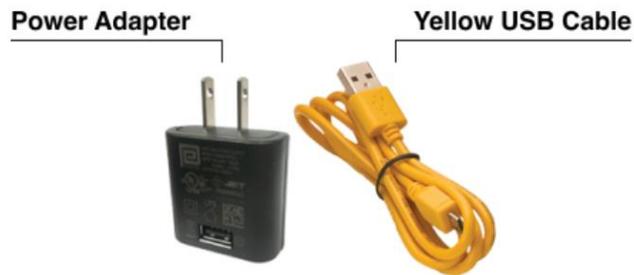
Manufacturer	Contact information
Abbott	Phone: Contact Abbott at 1-855-632-8658 (8:00 a.m. - 8:00 p.m. EST, 7 days a week) Website <ul style="list-style-type: none">• www.freestylebattery.com



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Sample Image of Abbott Provided Yellow USB Cable and Power Adapter

The Abbott provided yellow USB cable and power adapter, that are included in your Reader Kit, are shown here.



Members can contact Abbott if they need to request a replacement power adapter or yellow USB cable.

Abbott is Recalling Readers for the following FreeStyle Libre Glucose Monitoring Systems

Product Description	Product Models
<ul style="list-style-type: none">○ FreeStyle Libre Flash Glucose Monitoring System○ FreeStyle Libre 14 day Flash Glucose Monitoring System○ FreeStyle Libre 2 Flash Glucose Monitoring System	All Reader serial numbers

References:

1. FDA Medical Device Recall. Abbott Recalls the Readers used with the FreeStyle Libre, FreeStyle Libre 14 day, and FreeStyle Libre 2 Flash Glucose Monitoring Systems for Risk of Extreme Heat and Fire. FDA website. <https://www.fda.gov/medical-devices/medical-device-recalls/abbott-recalls-readers-used-freestyle-libre-freestyle-libre-14-day-and-freestyle-libre-2-flash>. Accessed April 17, 2023.
2. Abbott Press Release. Abbott Issues Safety Notification for FreeStyle Libre® Family of Readers in the U.S. Abbott website. <https://abbott.mediaroom.com/Abbott-Issues-Safety-Notification-for-FreeStyle-Libre-Family-of-Readers-in-the-U-S>. Accessed April 17, 2023.
3. FreeStyle Libre 2 User Manual. FreeStyle website. https://freestyleserver.com/Payloads/IFU/2023/q1/ART43994-501_rev-A-WEB.pdf. Accessed April 17, 2023.



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